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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
HAND, MELANIE JO	
ART UNIT	PAPER NUMBER
3761	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/670,861	SCHON ET AL.	
	Examiner	Art Unit	
	MELANIE J. HAND	3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 February 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *22-27,29-35 and 66-105* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *22-27 29-35 and 66-105* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on February 1, 2010 has been entered.

Response to Arguments

2. Applicant's arguments, see Remarks, filed February 1, 2010, with respect to the objection to the claims, have been fully considered and are persuasive. The objection to the claims has been withdrawn.

3. Applicant's arguments with respect to the claim rejections under 35 U.S.C. 112 have been fully considered and are persuasive. The claim rejections under 35 U.S.C. 112 have been withdrawn.

4. Applicant's arguments filed February 1, 2010 with respect to the rejections under 35 U.S.C. 103 have been fully considered but they are not persuasive.

5. With respect to arguments regarding claims 22, 35 and 88: As to the argument that Ash does not disclose an outer wall without the presence of ridges or grooves, it is the examiner's position that the leftover portion of membrane 46 after splitting the membrane would not be sufficient to define a ridge, especially in light of Ash's disclosure that the splitting of the membrane does not damage the surface of the outer wall of either lumen. It is the examiner's position also that the leftover portion of the membrane defines the membrane outer surface, not

the lumen outer surface, especially since the membrane is formed as a separate physical entity from the lumens. Therefore the leftover portion of the membrane is not a ridge on the outer surface. As to the argument that Davis only discloses one extrusion step and does not disclose further melting and extrusion, In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e. multiple and separate extrusion steps) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). As to the argument that the tipping process disclosed by Davis is a step of shaping the splittable tube and not for reattaching, it is the examiner's position that because the tipping process involves formation of the weakening lines that allow subsequent splitting as well as coextrusion, the tipping process can be used in the Ash method for reattachment of the split lumens just as well as it can be used to form splittable lumens such as those disclosed by Ash. The method of Ash is thus modified so as to include the coextrusion and melting steps to form a tip as disclosed by Davis. The fact that such a method yields a catheter that can once more be split is immaterial. The method of the combined teaching meets the claims.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

8. Claims 22-25, 27, 29, 30, 33-35 and 66-105 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ash et al (U.S. Patent No. 5,947,953) in view of Davis et al (WO 00/15289 A1).

With respect to **Claim 22:** With respect to the step of forming a unitary catheter tube, Ash teaches forming a unitary catheter tube in the form of double catheter assembly 10 having a distal portion and a distal end portion terminating in a distal end, a proximal portion terminating in a proximal end, an outer wall having a smooth, curved and generally convex surface without grooves and first and second lumens 28 and 32 of catheters 26, 30, respectively. Examiner's position regarding whether the outer wall of the unitary tube has a surface without grooves is based upon Ash's disclosure that the membrane 46 is formed such that splitting along said membrane to separate catheters 26 and 30 does not damage the outer surfaces of the catheters. (Col. 6, lines 36-40) Each of the first and second lumens necessarily extends longitudinally through the unitary catheter tube, as the first and second lumens are integral to the unitary tube prior to separation along said membrane.

With respect to the step of splitting the unitary catheter tube, Ash teaches partial splitting of septum 46 longitudinally along said distal end portion of unitary catheter tube 10 to form a first distal end tube 26 and second distal end tube 30.

With respect to the step of bonding at least a portion of the first distal end tube to the second to releasably attach the tubes, Ash discloses two distal end tubes and the steps of forming a unitary catheter and then splitting the unitary tube to form the first and second tubes, but does not disclose that the membrane 46 is formed by first splitting the unitary tube and then subsequently bonding portions of the distal tubes to one another to releasably attach the distal tubes. Davis discloses a method of forming a splittable catheter comprising the step of forming a unitary catheter tube, forming weakened portions that necessitate an initial splitting of the tubes to adhere stripes containing preferential tear lines 12, melting and extruding the already-split tubes with stripes thereon to one another to form said preferential tear lines, i.e. bonding at least a portion of a first distal end tube to a second distal end tube to form preferential tear lines to releasably attach the first and second distal end tubes. Davis discloses that this overcomes limitations of previous prior art splittable catheter formation methods wherein a certain tip configuration is desired and where the extruding step would eliminate the tear lines or cut lines, rendering the catheter no longer splittable. Therefore, it would be obvious to one of ordinary skill in the art to modify the method of Ash such that the splittable membrane is formed in an identical manner to the stripe and preferential tear line disclosed by Davis to prevent loss of pre-determined cut lines during subsequent formation steps that would eliminate the splittable capability of the catheter. (‘289, Page 4, ¶1 - Page 6, ¶1) The method of Ash as modified by Davis thus meets the limitation of a method comprising the step of bonding at least a portion of the first distal end tube to the second distal end tube to releasably attach the first and second distal end tubes. The method of Ash as modified by Davis also thus meets the functional

limitation “whereby the multilumen catheter assembly assists prevention of leakage at a vessel entry site through use of the unitary catheter tube outer wall while providing length variability to separate independent distal end tubes."

With respect to **Claims 23,25:** Ash teaches that the catheter assembly 10 has a generally circular cross-section and that the catheters 26,30 have a semi-circular cross section wherein respective flat surfaces 38,44 are facing one another therefore the cross section of assembly 10 would be oval. (Fig. 4F) (Col. 6, lines 1-8, Col. 7, lines 31-35)

With respect to **Claim 24:** Ash teaches that the cross sections of lumens 28,32 are circular. (Col. 7, lines 31-37)

With respect to **Claim 26:** Ash teaches that the cannulating portion 20 is formed in a single extrusion process yielding catheters with a semicircular cross section. The single extrusion process includes a step of finishing an exterior of the first and second distal end tubes by virtue of the nature of the process itself, i.e. the molten plastic forming material is drawn through a die which forms the exterior, and positive pressure is applied thereto to form the hollow space of the catheter (the lumen) as an additional step after applying the molten material to the die, thereby casting the molten material into the catheter shape with its semicircular cross section and finished exterior.

With respect to **Claim 27:** In the method of Ash as modified by Davis, the first and second distal end tubes are releasably attached by bonding via melting and extrusion of the stripe and main body portions of the split tubes over the portion of the longitudinal length where the first and

second distal end tubes have a generally semi-circular shape in cross-section. The motivation to modify the method of Ash such that the splittable membrane is formed as a stripe with a preferential tearline by extrusion as disclosed by Davis is stated *supra* with respect to claim 22.

With respect to **claim 29:** In the method of Ash as modified by Davis, the first and second distal end tubes are bonded via melting and extrusion of the stripe and main body portions of the split tubes to provide releasable attachment along said tear lines disclosed by Davis beginning at a point where the first and second distal end tubes begin to extend from the unitary catheter tube, continuing over a proximal portion of their longitudinal lengths and are separate over a distal portion of their longitudinal lengths to the distal end. The motivation to modify the method of Ash such that the splittable membrane is formed as a stripe with a preferential tearline by extrusion as disclosed by Davis is stated *supra* with respect to claim 22.

With respect to **Claim 30:** Ash teaches separating catheters 26 and 30 along a portion of membrane 46 wherein the length of the split region is greater than the unitary region. (Fig. 1) (Col. 6, lines 42-45)

With respect to **Claim 33,34:** Ash teaches that the cannulating portion 20 of catheter assembly 10 is formed from an extrusion process. (Col. 12, lines 38-41)

With respect to **claim 35:** Ash teaches a method of making a multilumen catheter assembly, comprising the steps of: forming a unitary catheter tube in the form of double catheter tube assembly 10 to have a distal portion and a distal end portion terminating in a distal end, a proximal portion terminating in a proximal end, and a first lumen 28 and a second lumen 32.

Each of the first and the second lumens 28,32 extends longitudinally through the unitary catheter tube. (Fig. 1) Ash teaches splitting the unitary catheter tube longitudinally via frangible membrane 46 along the distal end portion to form a first distal end tube and a second distal end tube, thereby creating a point of transition between split and unsplit portions of the unitary catheter tube 10, wherein a length of the split portion of the unitary catheter tube, defined as the length from the transition point to the distal end, is greater than a length of the unitary catheter tube from the proximal end to the transition point inasmuch as Ash teaches that the catheters 26,30 defining lumens 28,32 are split along the full length of catheter 10 up to hub 24 (Fig. 1, Col. 11, lines 56-61). The first and the second distal end tubes are separate from the transition point (hub 24) to the distal end, whereby the first and the second distal end tubes are splittable by minimal force via frangible membrane 46 from the transition point to the bonding point and independent and free floating from the bonding point to the distal end.

With respect to the step of bonding at least a portion of the first distal end tube to the second to releasably attach the tubes, Ash discloses two distal end tubes and the steps of forming a unitary catheter and then splitting the unitary tube to form the first and second tubes. However, Ash does not disclose releasably re-attaching the first and the second distal end tubes to one another along a partial portion of their longitudinal lengths, the first and the second distal end tubes being releasably re-attached from the transition point to a bonding point located between the transition point and the distal end. Davis discloses a method of forming a splittable catheter comprising the step of forming a unitary catheter tube, forming weakened portions that necessitate an initial splitting of the tubes to adhere stripes containing preferential tear lines 12, melting and extruding the already-split tubes with stripes thereon to one another to form said preferential tear lines, i.e. bonding at least a portion of a first distal end tube to a second distal end tube to form preferential tear lines to releasably attach the first and second distal end tubes.

Davis discloses that this overcomes limitations of previous prior art splittable catheter formation methods wherein a certain tip configuration is desired and where the extruding step would eliminate the tear lines or cut lines, rendering the catheter no longer splittable. Therefore, it would be obvious to one of ordinary skill in the art to modify the method of Ash such that the splittable membrane is formed in an identical manner to the stripe and preferential tear line disclosed by Davis to prevent loss of pre-determined cut lines during subsequent formation steps that would eliminate the splittable capability of the catheter. ('289, Page 4, ¶1 - Page 6, ¶1) The method of Ash as modified by Davis thus meets the limitation of a method comprising the step of releasably re-attaching the first and the second distal end tubes to one another along a partial portion of their longitudinal lengths, the first and the second distal end tubes being releasably re-attached from the transition point to a bonding point located between the transition point and the distal end. The method of Ash as modified by Davis also thus meets the functional limitation "whereby the multilumen catheter assembly assists prevention of leakage at a vessel entry site through use of the unitary catheter tube outer wall while providing length variability to separate independent distal end tubes."

With respect to **claim 66:** Ash does not disclose the step of releasably re-attaching. Davis discloses the step of releasably re-attaching first and second distal end tubes wherein releasably re- attaching the first and the second distal end tubes involves heat molding. ('289, Page 6) The motivation to modify the method of Ash to include the step of releasably re-attaching the first and second distal end tubes as disclosed by Davis is stated *supra* with respect to claim 35.

With respect to **claim 67:** Ash does not disclose the step of releasably re-attaching. Davis discloses the step of releasably re-attaching first and second distal end tubes wherein releasably re- attaching the first and the second distal end tubes employs an adhesive stripe having an adhesive strength relative to a material forming the first and the second distal end tubes that is greater than a cohesive strength of the adhesive. ('289, Page 5, ¶1) The motivation to modify the method of Ash to include the step of releasably re-attaching the first and second distal end tubes as disclosed by Davis is stated *supra* with respect to claim 35.

With respect to **claim 68:** Ash does not disclose the step of releasably re-attaching. Davis discloses the step of releasably re-attaching first and second distal end tubes wherein releasably re- attaching the first and the second distal end tubes employs an adhesive stripe, wherein the adhesive is applied as a partial coating, namely a stripe, on one or both of outer walls of the first and the second distal end tubes, whereby when the tubes are pressed together, the outer walls adhere. ('289, Page 5, ¶¶1,2)

With respect to **claim 69:** The multilumen catheter assembly disclosed by Ash is a hemodialysis catheter assembly. (Col. 5, lines 15-19)

With respect to **claim 70:** The multilumen catheter assembly disclosed by Ash is adapted to remove and introduce bodily fluids, medicaments and other fluid solutions from and to a body. (Col. 5, lines 15-19)

With respect to **claim 71:** The unitary catheter tube 10 disclosed by Ash is a single, flexible multilumen tube. (Col. 8, lines 55-59)

With respect to **claim 72:** The step of forming the unitary catheter tube involves manufacturing by molding. (Col. 10, lines 12-17)

With respect to **claim 73:** In the method of Ash, the terms “distal” and “distal end” refer to a direction closer to an insertion tip of the catheter and the terms “proximal” and “proximal end” refer to a direction away from the insertion tip of the catheter, inasmuch as distal end tubes 26 and 30 are closer to the insertion tip of the catheter. (Fig. 1)

With respect to **claim 74:** The first and the second lumens 28, 32, respectively, disclosed by Ash extend longitudinally through a full length of the unitary catheter tube and the multilumen catheter assembly.

With respect to **claim 75:** Ash does not explicitly disclose that splitting the unitary catheter tube involves sharp edge cutting over a pre-determined distance. Davis discloses that it is known in the art to form a splittable catheter from a unitary catheter by skiving, i.e. sharp-edge cutting. As such cutting would accomplish the identical goal of splitting the catheter tube into separate distal end tubes equally well compared to providing a splittable membrane, it would be obvious to one of ordinary skill in the art to modify the method of Ash such that splitting the unitary catheter tube involves sharp edge cutting over a pre-determined distance as disclosed by Davis to provide a means for separating the unitary catheter into separate catheters for effective drainage.

With respect to **claim 76:** Ash does not disclose the step of bonding as claimed. Davis discloses the step of bonding a first distal end tube to a second distal end tube wherein the step of bonding involves adhering the first distal tube to the second distal tube to releasably re-attach the first and the second distal end tubes, inasmuch as the step of bonding employs an adhesive stripe. whereby when the tubes are pressed together, the outer walls adhere. ('289, Page 5, ¶¶1,2) The motivation to modify the method of Ash to include the step of bonding to releasably re-attach the first and second distal end tubes as disclosed by Davis is stated *supra* with respect to claim 35.

With respect to **claims 77,79:** Ash does not disclose releasable reattachment as claimed after the step of splitting. Davis discloses the step of releasably re-attaching first and second distal end tubes wherein releasably re- attaching the first and the second distal end tubes employs an adhesive stripe having an adhesive strength relative to a material forming the first and the second distal end tubes that is greater than a cohesive strength of the adhesive, i.e. the adhesive includes properties causing the adhesive to adhere more strongly to the tubes than to itself, whereby application of opposing transverse forces to the distal end tubes causes the adhesive to lose cohesive strength and separate longitudinally along the catheter assembly without structurally altering the distal end tubes. ('289, Page 5, ¶1) The motivation to modify the method of Ash to include the step of releasably re-attaching the first and second distal end tubes as disclosed by Davis is stated *supra* with respect to claim 35.

With respect to **claim 78:** Ash does not disclose the step of releasably re-attaching. Davis discloses the step of releasably re-attaching first and second distal end tubes wherein releasably re- attaching the first and the second distal end tubes employs an adhesive stripe,

wherein the adhesive is applied as a partial coating, namely a stripe, on one or both of outer walls of the first and the second distal end tubes, whereby when the tubes are pressed together, the outer walls adhere. ('289, Page 5, ¶¶1,2)

With respect to **claim 80:** As can be seen in Fig. 1 of Ash, the first distal end tube is attached to the second distal end tube over an entire length of a shorter of the first and the second distal end tubes. Ash does not disclose the step of bonding as claimed subsequent to splitting. Davis discloses the step of bonding a first distal end tube to a second distal end tube wherein the step of bonding involves adhering the first distal tube to the second distal tube to releasably re-attach the first and the second distal end tubes, inasmuch as the step of bonding employs an adhesive stripe. whereby when the tubes are pressed together, the outer walls adhere. ('289, Page 5, ¶¶1,2) The motivation to modify the method of Ash to include the step of bonding to releasably re-attach the first and second distal end tubes as disclosed by Davis is stated *supra* with respect to claim 22. The first distal end tube of the method of Ash as modified by Davis is thus bonded to the second distal end tube over an entire length of a shorter of the first and the second distal end tubes.

With respect to **claim 81:** The multilumen catheter assembly disclosed by Ash is a hemodialysis catheter assembly. (Col. 5, lines 15-19)

With respect to **claim 82:** The multilumen catheter assembly disclosed by Ash is adapted to remove and introduce bodily fluids, medicaments and other fluid solutions from and to a body. (Col. 5, lines 15-19)

With respect to **claim 83:** The unitary catheter tube 10 disclosed by Ash is a single, flexible multilumen tube. (Col. 8, lines 55-59)

With respect to **claim 84:** The step of forming the unitary catheter tube involves manufacturing by molding. (Col. 10, lines 12-17)

With respect to **claim 85:** In the method of Ash, the terms “distal” and “distal end” refer to a direction closer to an insertion tip of the catheter and the terms “proximal” and “proximal end” refer to a direction away from the insertion tip of the catheter, inasmuch as distal end tubes 26 and 30 are closer to the insertion tip of the catheter. (Fig. 1)

With respect to **claim 86:** The first and the second lumens 28, 32, respectively, disclosed by Ash extend longitudinally through a full length of the unitary catheter tube and the multilumen catheter assembly.

With respect to **claim 87:** Ash does not explicitly disclose that splitting the unitary catheter tube involves sharp edge cutting over a pre-determined distance. Davis discloses that it is known in the art to form a splittable catheter from a unitary catheter by skiving, i.e. sharp-edge cutting. As such cutting would accomplish the identical goal of splitting the catheter tube into separate distal end tubes equally well compared to providing a splittable membrane, it would be obvious to one of ordinary skill in the art to modify the method of Ash such that splitting the unitary catheter tube involves sharp edge cutting over a pre-determined distance as disclosed by Davis to provide a means for separating the unitary catheter into separate catheters for effective drainage.

With respect to **claim 88:** Ash discloses a method of making a multilumen catheter assembly. With regard to the step of forming a unitary catheter tube, Ash discloses the step of forming unitary catheter tube 10 having the following: an outer surface having a generally smooth, circular cross-sectional shape without ridges or grooves; a distal portion terminating in a distal end and a proximal portion terminating in a proximal end; and a first lumen 28 and a second lumen 32 separated therein by an internal septum 46, wherein the first lumen and the second lumen each have a generally semi-circular cross- sectional shape (Fig. 4a), and the first lumen, the second lumen and the internal septum each extend longitudinally through a full length of the unitary catheter tube 10.

With regard to the step of splitting, Ash discloses splitting the unitary catheter tube longitudinally along septum 46 along the distal portion to form a first distal end tube 26 and a second distal end tube 30 each having an outer surface generally semi-circular in cross-sectional shape (Fig.4a).

With respect to the step of releasably attaching at least a portion of the first distal end tube to the second to releasably attach the tubes, Ash discloses two distal end tubes and the steps of forming a unitary catheter and then splitting the unitary tube to form the first and second tubes. However, Ash does not disclose releasably attaching the first and the second distal end tubes to one another, subsequent to the step of splitting, along a partial portion of their longitudinal lengths, the first and the second distal end tubes being releasably re-attached from the transition point to a bonding point located between the transition point and the distal end. Davis discloses a method of forming a splittable catheter comprising the step of forming a unitary catheter tube, forming weakened portions that necessitate an initial splitting of the tubes to adhere stripes containing preferential tear lines 12, melting and extruding the already-split

tubes with stripes thereon to one another to form said preferential tear lines, i.e. bonding at least a portion of a first distal end tube to a second distal end tube to form preferential tear lines to releasably attach the first and second distal end tubes. Davis discloses that this overcomes limitations of previous prior art splittable catheter formation methods wherein a certain tip configuration is desired and where the extruding step would eliminate the tear lines or cut lines, rendering the catheter no longer splittable. Therefore, it would be obvious to one of ordinary skill in the art to modify the method of Ash such that the splittable membrane is formed in an identical manner to the stripe and preferential tear line disclosed by Davis to prevent loss of pre-determined cut lines during subsequent formation steps that would eliminate the splittable capability of the catheter. (‘289, Page 4, ¶1 - Page 6, ¶1) The method of Ash as modified by Davis thus meets the limitation of a method comprising the step of releasably re-attaching the first and the second distal end tubes to one another along a partial portion of their longitudinal lengths, the first and the second distal end tubes being releasably re-attached from the transition point to a bonding point located between the transition point and the distal end. The method of Ash as modified by Davis also thus meets the functional limitation “whereby the multilumen catheter assembly assists prevention of leakage at a vessel entry site through use of the unitary catheter tube outer wall while providing length variability to separate independent distal end tubes."

With respect to **claim 89:** Ash discloses that the unitary catheter tube is split a distance of about 3 cm extending along the distal portion from the distal end, which does not fall within or overlap the claimed range. However, since this range is not supported by applicant’s disclosure, there is no criticality assigned to this range by applicant. Since a greater splitting distance would allow for more maneuverability and access, the splitting distance is considered herein to be a

result-effective variable, and the claimed range is considered an optimization of a result-effective variable. It would be obvious to one of ordinary skill in the art to modify the splitting distance of Ash by increasing the distance from about 3 cm to a distance between about 4 cm and about 9 cm to allow such increased flexibility and maneuverability. It has been held that the discovery of an optimum value of a result-effective variable in a known process is ordinarily within the skill of the art. See *In re Boesch and Slaney*, 205 USPQ 215 (C.C.P.A. 1980)

With respect to **claim 90:** Ash discloses a first tube 26 that is shorter than the second tube 30 but does not disclose cutting a length of the first distal end tube so that the first distal end tube is shorter than the second distal end tube. It is examiner's position that it would be readily apparent and thus obvious to one of ordinary skill in the art to form the shorter end from the split tube by cutting a length of the first distal tube so that it is shorter than the second distal end tube. Ash discloses that this facilitates formation of drain openings during the manufacturing process (Col. 11, lines 48-57), therefore it would be obvious to one of ordinary skill in the art to modify the method of Ash such that said method includes the step of cutting a length of the first distal end tube so that said first distal tube is shorter than the second distal tube with a reasonable expectation of success to facilitate creation of drain openings or other formation steps involving the two distal end tubes.

With respect to **claim 91:** Ash discloses that the shorter first distal end tube is 6.82 inches, ±0.25 inches, which does not overlap the claimed range of about 5 cm to 6 cm in length. However, since this range is not supported by applicant's disclosure, there is no criticality assigned to this range by applicant. Since a greater difference in length between the first and second distal end tubes would further facilitate additional formation steps such as creating drain

openings, the difference in length is considered herein to be a result-effective variable, i.e. the greater the difference the easier the subsequent formation step of creating drain openings would be. Thus the claimed range is considered an optimization of a result-effective variable. It would be obvious to one of ordinary skill in the art to modify the splitting distance of Ash by shortening the first, shorter distal end tube such that its length falls within the claimed range to facilitate any subsequent formation steps such as creating drain openings. It has been held that the discovery of an optimum value of a result-effective variable in a known process is ordinarily within the skill of the art. See *In re Boesch and Slaney*, 205 USPQ 215 (C.C.P.A. 1980)

With respect to **claim 92:** The first distal end tube 26 having length L(c1) is 2.95 cm shorter than the second distal end tube 30 having length L (c2), which falls within the claimed range of between about 3 cm to 4 cm shorter, inasmuch a sthe examiner consideres 2.95 cm to be "about 3 cm." (Col. 7, lines 14-19)

With respect to **claim 93:** Ash does not disclose the step of releasably re-attaching. Davis discloses the step of releasably re-attaching first and second distal end tubes wherein releasably re- attaching the first and the second distal end tubes involves heat molding. ('289, Page 6) The motivation to modify the method of Ash to include the step of releasably re-attaching the first and second distal end tubes as disclosed by Davis is stated *supra* with respect to claim 35.

With respect to **claim 94:** Ash does not disclose the step of releasably re-attaching. Davis discloses the step of releasably re-attaching first and second distal end tubes wherein releasably re- attaching the first and the second distal end tubes employs an adhesive stripe

having an adhesive strength relative to a material forming the first and the second distal end tubes that is greater than a cohesive strength of the adhesive. ('289, Page 5, ¶1) The motivation to modify the method of Ash to include the step of releasably re-attaching the first and second distal end tubes as disclosed by Davis is stated *supra* with respect to claim 35.

With respect to **claim 95:** Ash does not disclose the step of releasably re-attaching. Davis discloses the step of releasably re-attaching first and second distal end tubes wherein releasably re- attaching the first and the second distal end tubes employs an adhesive stripe, wherein the adhesive is applied as a partial coating, namely a stripe, on one or both of outer walls of the first and the second distal end tubes, whereby when the tubes are pressed together, the outer walls adhere. ('289, Page 5, ¶¶1,2)

With respect to **claim 96:** The multilumen catheter assembly disclosed by Ash is a hemodialysis catheter assembly. (Col. 5, lines 15-19)

With respect to **claim 97:** The multilumen catheter assembly disclosed by Ash is adapted to remove and introduce bodily fluids, medicaments and other fluid solutions from and to a body. (Col. 5, lines 15-19)

With respect to **claim 98:** The unitary catheter tube 10 disclosed by Ash is a single, flexible multilumen tube. (Col. 8, lines 55-59)

With respect to **claim 99:** The step of forming the unitary catheter tube involves manufacturing by molding. (Col. 10, lines 12-17)

With respect to **claim 100:** In the method of Ash, the terms “distal” and “distal end” refer to a direction closer to an insertion tip of the catheter and the terms “proximal” and “proximal end” refer to a direction away from the insertion tip of the catheter, inasmuch as distal end tubes 26 and 30 are closer to the insertion tip of the catheter. (Fig. 1)

With respect to **claim 101:** Ash does not explicitly disclose that splitting the unitary catheter tube involves sharp edge cutting over a pre-determined distance. Davis discloses that it is known in the art to form a splittable catheter from a unitary catheter by skiving, i.e. sharp-edge cutting. As such cutting would accomplish the identical goal of splitting the catheter tube into separate distal end tubes equally well compared to providing a splittable membrane, it would be obvious to one of ordinary skill in the art to modify the method of Ash such that splitting the unitary catheter tube involves sharp edge cutting over a pre-determined distance as disclosed by Davis to provide a means for separating the unitary catheter into separate catheters for effective drainage.

With respect to **claim 102:** Ash teaches a method of making a multilumen catheter assembly, comprising the steps of: forming a unitary catheter tube in the form of double catheter tube assembly 10 to have a distal portion and a distal end portion terminating in a distal end, a proximal portion terminating in a proximal end, and a first lumen 28 and a second lumen 32. Each of the first and the second lumens 28,32 extends longitudinally through the unitary catheter tube. (Fig. 1) Ash teaches splitting the unitary catheter tube longitudinally via frangible membrane 46 along the distal end portion to form a first distal end tube and a second distal end tube, thereby creating a point of transition between split and unsplit portions of the unitary

catheter tube 10, wherein a length of the split portion of the unitary catheter tube, defined as the length from the transition point to the distal end, is greater than a length of the unitary catheter tube from the proximal end to the transition point inasmuch as Ash teaches that the catheters 26,30 defining lumens 28,32 are split along the full length of catheter 10 up to hub 24 (Fig. 1, Col. 11, lines 56-61). The first and the second distal end tubes are separate from the transition point (hub 24) to the distal end, whereby the first and the second distal end tubes are splittable by minimal force via frangible membrane 46 from the transition point to the bonding point and independent and free floating from the bonding point to the distal end.

With respect to the step of bonding at least a portion of the first distal end tube to the second to releasably attach the tubes, Ash discloses two distal end tubes and the steps of forming a unitary catheter and then splitting the unitary tube to form the first and second tubes. However, Ash does not disclose releasably re-attaching the first and the second distal end tubes to one another along a partial portion of their longitudinal lengths, the first and the second distal end tubes being releasably re-attached from the transition point to a bonding point located between the transition point and the distal end. Davis discloses a method of forming a splittable catheter comprising the step of forming a unitary catheter tube, forming weakened portions that necessitate an initial splitting of the tubes to adhere stripes containing preferential tear lines 12, melting and extruding the already-split tubes with stripes thereon to one another to form said preferential tear lines, i.e. bonding at least a portion of a first distal end tube to a second distal end tube to form preferential tear lines to releasably attach the first and second distal end tubes. Davis discloses that this overcomes limitations of previous prior art splittable catheter formation methods wherein a certain tip configuration is desired and where the extruding step would eliminate the tear lines or cut lines, rendering the catheter no longer splittable. Therefore, it would be obvious to one of ordinary skill in the art to modify the method of Ash such that the

splittable membrane is formed in an identical manner to the stripe and preferential tear line disclosed by Davis to prevent loss of pre-determined cut lines during subsequent formation steps that would eliminate the splittable capability of the catheter. (‘289, Page 4, ¶1 - Page 6, ¶1) The method of Ash as modified by Davis thus meets the limitation of a method comprising the step of releasably re-bonding the first and the second distal end tubes to one another along a partial portion of their longitudinal lengths, the first and the second distal end tubes being releasably re-attached from the transition point to a bonding point located between the transition point and the distal end. The method of Ash as modified by Davis also thus meets the functional limitation “whereby the multilumen catheter assembly assists prevention of leakage at a vessel entry site through use of the unitary catheter tube outer wall while providing length variability to separate independent distal end tubes."

With respect to **claim 103:** Ash does not explicitly disclose that splitting the unitary catheter tube involves sharp edge cutting over a pre-determined distance. Davis discloses that it is known in the art to form a splittable catheter from a unitary catheter by skiving, i.e. sharp-edge cutting. As such cutting would accomplish the identical goal of splitting the catheter tube into separate distal end tubes equally well compared to providing a splittable membrane, it would be obvious to one of ordinary skill in the art to modify the method of Ash such that splitting the unitary catheter tube involves sharp edge cutting over a pre-determined distance as disclosed by Davis to provide a means for separating the unitary catheter into separate catheters for effective drainage.

With respect to **claim 104:** Ash does not disclose the step of releasably re-attaching. Davis discloses the step of releasably re-attaching first and second distal end tubes wherein

releasably re- attaching the first and the second distal end tubes employs an adhesive stripe having an adhesive strength relative to a material forming the first and the second distal end tubes that is greater than a cohesive strength of the adhesive. ('289, Page 5, ¶1) The motivation to modify the method of Ash to include the step of releasably re-attaching the first and second distal end tubes as disclosed by Davis is stated *supra* with respect to claim 35.

With respect to **claim 105:** Ash does not disclose the step of releasably re-attaching. Davis discloses the step of releasably re-attaching first and second distal end tubes wherein releasably re- attaching the first and the second distal end tubes employs an adhesive stripe, wherein the adhesive is applied as a partial coating, namely a stripe, on one or both of outer walls of the first and the second distal end tubes, whereby when the tubes are pressed together, the outer walls adhere. ('289, Page 5, ¶¶1,2)

9. Claims 31 and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ash ('953) in view of Davis et al ('289), as applied to claim 22 above, and further in view of Melsky et al (U.S. Patent No. 5,704,915).

With respect to **Claims 31,32:** Neither Ash nor Davis discloses grinding or polishing the cannulating portion 20 of catheter assembly 10. Melsky teaches a hemodialysis access device comprised of a catheter with a proximal and distal end where the distal end is split into two conduits. Melsky teaches pumping a slurry of abrasive material through shells 22 and polishing the subsequently smoothed surfaces of conical shells 22 and outlet tubes 32. Melsky teaches that it is desirable to have blood contacting surfaces be as smooth as possible to avoid

thrombus formation and blood cell damage. ('915, Col. 5, lines 13-22) Since the assembly of the method of Ash as modified by Davis is also used for hemodialysis (Col. 5, lines 42-44), it would be obvious to one of ordinary skill in the art to modify the method of Ash as modified by Davis by including the step of grinding and polish the outside surfaces of the catheter assembly as disclosed by Melsky such that the outer surfaces of the distal end tubes are as smooth as possible to avoid thrombus formation and blood cell damage.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MELANIE J. HAND whose telephone number is (571)272-6464. The examiner can normally be reached on Mon-Thurs 8:00-5:30, alternate Fridays 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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/Melanie J Hand/

Primary Examiner, Art Unit 3761